

availability for an initial rapid burst of therapeutic action.

CLAIMS

Cancel claims 1, 11, 12, 17, 18 and 21-23 without prejudice or disclaimer and substitute the following new claims 24-31.

24. A method for treating Parkinson's disease which provides rapid and sustained symptomatic relief, principally avoiding delay in therapeutic onset of action, by administering a bilayer tablet formulation comprising an immediate release layer of 10-25 mg carbidopa and 50-200 mg levodopa and a sustained release layer of 25-75 mg carbidopa and 100-400 mg levodopa.

25. A method according to claim 24, the bilayer tablet comprising a sustained release core layer of carbidopa-levodopa overcoated by an immediate release layer of carbidopa-levodopa.

26. The pharmaceutical composition of claim 25, wherein at least one sustained release layer of carbidopa-levodopa is separated from at least one immediate release layer of carbidopa-levodopa by an excipient layer

which is drug-free and does not contain rate-controlling polymers.

27. A method according to claim 25, wherein said method avoids significant onset delay in effecting such treatment, said immediate release layer providing rapid onset of antiparkinson activity and said sustained release layer providing sustained antiparkinson activity.

28. A method according to claim 25, wherein said method avoids significant onset delay in effecting such treatment and avoids on-off phenomena in such treatment, said oral dosage formulation consisting of said immediate release layer and said sustained release layer, said immediate release layer providing rapid onset of antiparkinson activity and said sustained release layer providing sustained antiparkinson activity.

29. A method for treating Parkinson's disease in a patient having need of such treatment comprising orally administering at least one bilayer tablet to said patient, said tablet having a sustained release core layer consisting essentially of 25-75 mg carbidopa, 100-400 mg levodopa, methocel, micro-crystalline cellulose, croscarmellose sodium, silicon dioxide and magnesium

stearate, and an immediate release outer layer over said sustained release core layer, said immediate release layer consisting essentially of 10-25 mg carbidopa, 50-200 mg levodopa, microcrystalline cellulose, croscarmellose sodium, silicon dioxide and magnesium stearate.

30. A method according to claim 29, wherein said immediate release outer layer contains 25 mg carbidopa, 100 mg levodopa, 224 mg microcrystalline cellulose, 15 mg croscarmellose sodium, 3.0 mg silicon dioxide and 3.0 mg magnesium stearate, and said sustained release core layer contains 50 mg carbidopa, 200 mg levodopa, 80 mg methocel, 61 mg microcrystalline cellulose, 15 mg croscarmellose sodium, 2.0 mg silicon dioxide and 2.0 mg magnesium stearate, the mg being mg/tablet.

31. A method according to claim 29, wherein said immediate release outer layer contains 12.5 mg carbidopa, 50 mg levodopa, 123.5 mg microcrystalline cellulose, 2.0 mg silicon dioxide and 10 mg magnesium stearate, and said sustained sustained release core contains 37.5 mg carbidopa, 150 mg levodopa, 80 mg methocel, 53.5 mg microcrystalline cellulose, 2.0 mg

Appln No. 08/835,482 (Rubin)

*E1
comment*
silicon dioxide and 2.0 mg magnesium stearate, the mg being mg/tablet.

COMMENT

Please enter this Amendment and Response and the new claims. The new claims find support in the original application. The specification amendments of June 5, 2002 rest on the original claims 1-10 and avoid new matter.

Favorable action on the merits is respectfully requested.

Respectfully submitted,



Alan A. Rubin, Applicant with
Approved Power of Attorney
For this Application

207 Hitching Post Drive
Wilmington, DE 19803
(T) 302, 478-0838